

# USER'S GUIDE

## *Nuvo LITE Mark 5*

### (OCSI)

#### OXYGEN CONCENTRATOR



**[Original language is English]**



Federal Law (US) restricts this device to sale by, or on the order of, a licensed physician. This oxygen concentrator should be used only under the supervision of a licensed physician.

**CE** 0413: Complies with the 93/42/ EEC directive  
certified by the approved organization no 0413.



**Danger: Do not smoke when using oxygen or when near this device.**

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## APPENDIX A EMC INFORMATION

## **GLOSSARY OF SYMBOLS**

 : ON (power switched on)	 : Do not use oil or grease
 : Off (power switched off)	 : Technical information
 : Type B device	 : Consult the accompanying documents
 : Class II protection	 : Keep in the vertical position
 : Do not expose to open flames	 : Fragile - handle with care
	 : Oxygen concentration warning light

## GENERAL SAFETY GUIDELINES

**Only persons who have read and understood this entire manual  
should be allowed to operate the *Nuvo LITE Mark 5*.**

### USE OF OXYGEN



Oxygen is not a flammable gas, but it accelerates the combustion of materials. To avoid all risks of fire, the *Nuvo LITE Mark 5* should be kept away from all flames, incandescent sources and sources of heat (cigarettes), as well as any combustible products such as oil, grease, solvents, aerosols, etc.



Do not use in an explosive atmosphere.



Avoid letting oxygen accumulate on an upholstered seat or other fabrics. If the concentrator is operating while not supplying oxygen to a patient, position it so that the gas flow is diluted in the ambient air.



Place the device in a ventilated area free from smoke and atmospheric pollution (rear filter unobstructed).



The *Nuvo LITE Mark 5* must only be used for oxygen therapy and only on a medical prescription. The indicated daily duration and flow must be followed, otherwise it may present a risk to the health of the patient.



Do not use in a specifically magnetic environment such as: (MRI, X-ray, etc.)

### USE AND MAINTENANCE OF THE DEVICE



Do not open the device while in operation: risk of electrical shock.



Use the power cord provided, and check that the electrical characteristics of the power socket used match those indicated on the manufacturer's plate on the rear panel of the machine.



We recommend against the use of extension cords or adapters, as they are potential sources of sparks and fire.



The *Nuvo LITE Mark 5* has an audible alarm to warn the user of problems. In order that the alarm may be heard, the maximum distance that the user can move away from it must be determined to suit the surrounding noise level.

### CONFORMITY WITH IEC60601-1 (§ 6.8.2 B):

"The manufacturer, assembler, installer or distributor are not considered to be responsible themselves for the consequences on the safety, reliability and characteristics of a device unless:

- The assembly, fitting, extensions, adjustments, modifications or repairs have been performed by persons authorized by the party in question,
- The electrical installation of the corresponding premises complies with local electrical codes. (e.g. IEC / NEC).
- The device is used in accordance with the instructions for use."

If the replacement parts used for the periodic servicing by an **approved** technician do not comply with the manufacturer's **specifications**, the manufacturer is not responsible in the event of an accident.

This device complies with the requirements of the FDA Quality System Regulation and the 93/42/EEC European directive but its operation may be affected by other devices being used near by, such as diathermy and high frequency electro-surgical equipment, defibrillators, short wave therapy equipment, mobile telephones, CB and other portable devices, microwave ovens, induction plates

or even remote control toys or any other electromagnetic interferences which exceed the levels specified by the EN 60601-1-2 standard.

### CONTRAINDICATIONS

An oxygen therapy may only be carried out under caution are:

- Patients in the old age
- Obesity
- Simultaneous ACTH or glucocorticoid-treatment
- Patients with high carbon dioxide concentration in arterial blood
- Poisoning with substances which reduce the respiratory activity
- Disorders of the respiratory control in the central nervous system
- Fever

The application of pure oxygen treatment should not be applied in the case of acute respiratory weakness (respiratory insufficiency on the basis of a chronic obstructive emphysema bronchitis) because of the impending decline of lung ventilation.

### ADVERSE REACTION

Considering the contraindications adverse reactions are not to be expected when used with

normal oxygen pressure. The oxygen respiration of patients with decreased pulmonary ventilation can lead to a rapid rise in carbon dioxide-values. In the case of treatment with 50% oxygen up to 7 days, no clinically significant symptoms were observed. 100% oxygen treatment for 24 hours instead leads to cellular and functional damage of the lung (cell changes of alveolar epithelium, secretion densification, restriction of cilia movement, Atelectasis and changes of the minute volume, carbon dioxide retention and pulmonary vasodilation).

This means that in cases of treatment with 1 atmosphere pressure over a longer time or at even higher air oxygen pressures after short treatment poisoning symptoms (hyboventilation, acidosis up to developing pulmonary oedema) can be expected. It should be noted that a too rapid reduction of the partial pressure of oxygen may lead to a life dangerous undersupply (Hypoxemia).

While medicating neonates, a long-lasting and highly concentrated (more than 40%) oxygen treatment may lead to blindness, caused by eye lens injury (retro lental Fibroplasia). Furthermore, there is the risk of bleeding (pulmonary haemorrhage), cellular and / or dysfunction in the lungs (focal atelectasis and hyaline membrane disease or neonatal respiratory distress syndrome - with diffuse pulmonary fibrosis). To avoid any development of such a lung collapse (Bronchopulmonary Dysplasia), it is essential to repeatedly test the oxygen pressure in arterial (oxygenated) blood during the treatment.

### **I. DESCRIPTION**

The *Nuvo LITE Mark 5* is intended to supply supplemental oxygen to persons requiring low flow oxygen therapy. It is not intended to be life supporting or life sustaining. It produces oxygen enriched product by concentrating the oxygen contained in room air. It can be used either to administer oxygen with nasal cannulas or another probe or mask type of device.

The *Nuvo LITE Mark 5* is easy to use.

The single flow adjustment knob allows:

- the device to be easily adjusted to the prescribed flow rate,
- the equipment supplier or medical staff to limit flows to a specific flow rate with a built-in locking device.

It has a power failure alarm and an operating fault alarm.

**Note: the performances described pertain to the use of the *Nuvo LITE Mark 5* with the accessories recommended by Nidek Medical Products, Inc.**



**I.1. Front panel (Fig. I.1)**

- 1 - I/O (ON/OFF) Switch
- 2 - Indicator Lights
- 3 - Oxygen enriched air outlet
- 4 - Flow adjustment knob (l/min.)
- 5 -



**I.2. Rear panel (Fig. I.2)**

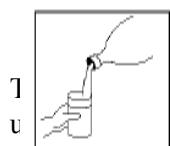
- 6 - Humidifier
- 7 - Filter
- 8 - Power Cord
- 9 - Hour meter
- 10 - Technical Label

## II. STARTING UP / INSTALLATION

### II.1. Use in direct oxygen therapy

a. Ensure that the switch (1) is in the **O** (OFF) position.

b. If used with a humidifier:



Unscrew the flask and fill it with water up to the line (see humidifier instructions). screw the lid on the humidifier flask there are no leaks.

c. Connect the oxygen tube to the humidifier outlet nozzle or to the concentrator outlet if a humidifier has not been prescribed. The tube between the cannula and the **Nuvo LITE Mark 5** should be limited to 20 meters (60 feet) long, in order to ensure that the oxygen flow rate remains within specification values.

d. Ensure that all of the parts are connected correctly so as to avoid leaks.

e. Plug the power cable into a power outlet of the correct voltage and frequency as defined on the manufacturer's technical label (Fig I2-10).



f. Press the power switch (**I/O**) to the ON position (**I**). The green indicator will light when the oxygen concentration exceeds the set point.

g. Turn the flow adjustment knob (4) to the prescribed value. This knob may have already been locked in the medically prescribed position. In this case, do not force it. Only the technician or medical personnel are authorized to release it.

h. Check that the oxygen flows out of the administration device (nasal cannulas or other) by placing the orifice(s) on the surface of a glass of water. The flow should disturb the surface of the water.

i. Adjust the nasal cannula to suit your face.

**Remark:** the required oxygen concentration is normally obtained within five minutes after the unit is started.

At the end of the treatment, press the **I/O** Switch to place it in the **O** (OFF) position to stop the device. The oxygen enriched air flow continues for approximately one minute after the device is stopped.

#### For the equipment supplier or medical staff:

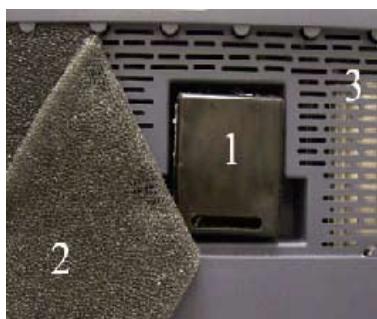
The flow adjustment knob may be locked to limit it to a specific predetermined value.

### III. CLEANING - MAINTENANCE

#### III.1. Cleaning

Only the outside of the ***Nuvo LITE Mark 5*** is to be cleaned, with a soft, dry cloth or, if necessary, a damp sponge, then thoroughly dried with wipes and an alcohol based solution. Acetone, solvents or any other inflammable products **must not be used**. Do not use abrasive powders.

The removable cabinet air filter (2) must be cleaned in warm water and household detergent weekly or after approximately 100 hours of use. More frequent cleaning is recommended in dusty environments



#### III.2. Daily disinfection

Because there is a bacterial filter inside the device, daily disinfection concerns only the external oxygen therapy accessories: humidifier, probes, nasal cannulas (refer to the respective instructions for use).

**The device must be switched off when alcohol based solutions are used.**

**a. The following minimum guidelines must be observed:**

- Humidifier : (If prescribed by a physician)

Daily:

- Empty the water from the humidifier.
- Rinse the humidifier flask under running water.
- Fill humidifier up to the mark with boiled water.

Regularly:

• Clean the humidifier with a soft soap sud. Rinse with clear water and dry. To ensure the complete removal of soap rest, fill the humidifier with water and let the humidifier connected to the device bubble for some minutes. Finalize this action substituting the water with boiled water.

- Check that the humidifier lid seal is in good condition.
- Oxygen tubing and nasal cannula:

Follow the manufacturer's instructions.

**b. For each new patient:**

The humidifier must be changed.

The ***Nuvo LITE Mark 5*** must be cleaned and disinfected as per the above instructions. The bacterial filter inside the device has to be changed. The cabinet air filter may be changed as well. The entire oxygen administration circuit (oxygen therapy nasal cannulas, etc.) must be changed.

#### III.3. Maintenance

No special maintenance needs to be carried out by the patient. Your equipment supplier performs periodic maintenance operations to assure continued reliable service from the ***Nuvo LITE Mark 5***.

### IV. USEFUL INFORMATION

#### IV.1. Accessories and spare parts

The accessories used with the ***Nuvo LITE Mark 5*** must:

- be oxygen compatible,
- be biocompatible,
- comply with the general requirements of the FDA Quality System Regulation or the 93/42/EEC European Directive as appropriate.

The connectors, tubes, nasal cannulas, probes or masks must be designed for oxygen therapy usage.

The accessories with a **Nidek Medical** part number reference, or included in the set of accessories supplied with the device, comply with these requirements. Contact your dealer to obtain these accessories.

**Remark:** The use of certain administration accessories which are not specified for use with this concentrator may reduce its performance and void the manufacturer's responsibility (ISO 8359).

#### AVAILABLE ACCESSORIES IF PRESCRIBED BY A PHYSICIAN

Humidifier*:	14 090 417
Cannula with 2 m (7 ft) tubing*:	14 090 510
Extension Tubing 7.7 m (25ft):	14 090 496
Tubing Adapter:	14 090 515
* Standard equipment	

#### IV.2. Materials in direct or indirect contact with the patient

Concentrator casing	ABS
Mains cable	PVC
Cabinet Air fFler	Polyester
I/O (On/Off) switch	Nylon
Casters	Nylon
Flow adjustment knob	ABS
Gas outlet	Stainless Steel
Printed labels	Polycarbonate
Pipe/Tubing	Aluminium, PVC, polyurethane or silicone
Humidifier	Polypropylene
Filter	Polypropylen

## IV.3. Operating principle

The compressor sends filtered ambient air to a solenoid valve, which allows compressed air to pass to the column in production. The columns contain a molecular sieve, whose function is to adsorb the nitrogen and thus allow oxygen to pass.

The oxygen enriched product is then directed to a pressure reducing valve through the adjustable flow valve to the oxygen outlet fitting.

During this time, the column which is being "regenerated" is connected to the ambient air and flow of oxygen enriched product is passed through it (from the column "in production"). In this way, when one column is in production, the other is in a nitrogen desorption or "regeneration" phase. The oxygen enriched product finally passes through a bacterial filter located prior to the oxygen outlet fitting.

## IV.4. Alarms - Safety devices

### IV.4.1. Alarms

- No voltage detection:

In the event of a loss of mains power, an intermittent audible alarm is activated and the green light turns off. Test alarm by actuating the **I/O** (On/Off) switch when the power cord is not plugged into the wall outlet.

- Process fault:

In the case of a process fault, a visible and audible alarm is activated (continuous red light or lighted alarm and audible alarm, see p. 7).

### IV.4.2. Safety devices

- Compressor motor:

Thermal safety is ensured by a thermal switch situated in the motor winding ( $145 \pm 5^\circ\text{C}$ ).

- Electrical protection of the **Nuvo LITE Mark 5** :

A 5A circuit breaker is incorporated into the front cabinet of all 230V models. A 10 A circuit breaker is included with 115V models.

- Safety valve:

This is fitted on the compressor outlet and is calibrated to 2.7 bar (40 psig).

- Class II devices with insulated castings (EN60601-1 standard)

## IV.5. OCSI (oxygen concentration status indication module) function

### IV.5.1. Operating principle

The Oxygen Monitor (2) is an electronic module capable of checking the effective oxygen concentration supplied by the **Nuvo LITE Mark 5** concentrator.

The Oxygen Monitor measures the concentration and activates an audible and visual alarm if it falls below the alarm set point percentage.

When the **Nuvo LITE Mark 5** is started, the indicator lights operate as follows:

### IV.5.2. Green indicator

The green (LED) indicator light indicates that power is applied to the concentrator and that it is ready to provide oxygen enriched air to the patient. To be lighted, it is necessary that the concentrator power plug be inserted into the wall outlet, that the **I/O** (On/Off) switch be actuated and that the oxygen concentration has reached the alarm set-point

### IV.5.3. Red indicator

The red (LED) indicator light is used to warn the patient of a system fault. The event that can cause the red (LED) indicator to be lighted is low oxygen concentration . The low oxygen concentration red (LED) warning will light when the oxygen concentration falls below a predetermined set point. When the red (LED) warning light is on for 15 minutes ( $\pm 2$  minutes), a continuous audible alarm is activated. A audible alarm will sound intermittently on loss of mains power. Call the equipment supplier to service the device.

### IV.5.4. Maintenance of the Device Alarms

- No special maintenance is required. The alarm set-point is factory set and the setting cannot be adjusted. Models operating at 50 Hz are set at 83% and 60 Hz models are set at 85%.
- The equipment supplier checks that the device is still operating correctly when the routine checks are performed on the **Nuvo LITE Mark 5** .

## IV.6. Technical characteristics

Dimensions: L x W x H: 36x23x58.5 cm (14 x 9 x 23 in.)  
Caster diameter: 3.8 cm (1.5 in.).  
Tilt angle (transport with humidifier fitted): 30°.  
Weight: 13 kg / 30 lbs (depends on model)  
Noise level < 40 dBA

### Flow values:

12 position flow valve 0.125-5 liters/minute.  
(Some models may have other values.)

**Accuracy of flow supplied:**

In compliance with the ISO 8359 standard, the flow supplied is equal to the flow set on the flowvalve, accurate to within  $\pm$  10 % or 200 ml/min, whichever is the larger of the two.

**Oxygen Concentration:**

- at 2 l/min: >90%.
- at 5 l/min: 90%. (+6.5%/-3%)

(Values at 21°C and at one atmosphere pressure).

Maximum recommended flow: 5 l/min.

The variation of the maximum recommended flow does not exceed  $\pm$  10 % of the indicated value when a back pressure of 7 kPa (1 psig) is applied to the output of the device. The maximum outlet pressure is 50 kPa (7 psig).

**Electrical power supply:**

	<b>115 V Units</b>	<b>230 V Units</b>
Frequency:	60 Hz	50 & 60 Hz
Average Power:	330 W(avg)	300 W(avg)
Protection Class:	Class II	Class II
Mains Protection:	10 A	5 A
On-time:	100 %	100 %

**Filters:**

At the rear of the device: a cabinet air filter.

At the compressor input: a filter cartridge, behind cabinet air filter. Before the oxygen outlet: a bacterial filter < 0.3  $\mu\text{m}$ . (technician only)

**Air circulation:**

A tubeaxial fan cools the compressor compartment

**Environmental limit conditions:**

The performances of the device (especially the oxygen concentration) are quoted at 21°C (70°F) and one atmosphere. They may change with temperature and altitude. For further information, please consult the maintenance manual.

- The device must be stored, transported and used in the vertical position only.
- Ambient temperature of between 5°C and 40°C (40°F to 104°F) operation.
- Storage temperature from -20°C to 60°C (-4°F to 160°F).
- Relative humidity of between 15 % and 95 % operation and storage, both non-condensing.
- Altitude(21°C): Up to 2,286m (7,500 ft) without degradation;

Consult your equipment provider for further information regarding 2,286m to 4000 m (7,500 to 13000 ft).

- Complies with EN60601-1 standard; spilling of a glass of water.

**IV. 7. Standards**

ISO 8359:1996 Oxygen concentrators for medical use.

EN 60601-1[UL60601-1:2003],CAN/CSA-C22.2 No.601.1-M90 w/A1&A2: Electrical Safety- Medical Devices.

EN60601-1-2:2001 Electromagnetic Compatibility

**IV.8. Method for disposing of waste**

All waste from the ***Nuvo LITE Mark 5*** (patient circuit, filter, etc.) must be disposed of using the methods appropriate to

the civil authority of the location where used.

**IV.9. Method for disposing of the device**

In order to preserve the environment, the concentrator must only be disposed of using the appropriate methods. All materials of construction are recyclable.

Furthermore, as part of the marking (directive 93/42/EEC), the serial number of the device disposed of must be sent to the **Nidek Medical** technical service department if the unit has the **CE** marking.

**IV.10. Warranty Period**

5 Years.

***Nuvo LITE Mark 5 Serial No.*** \_\_\_\_\_

**Date first used:** \_\_\_\_\_

**Maintained by:** \_\_\_\_\_

**Your distributor:** \_\_\_\_\_

**Address :** \_\_\_\_\_

**Telephone :** \_\_\_\_\_

**PREVENTIVE MAINTENANCE:**

- a. Wash cabinet filter weekly
- b. Replace air inlet filter annually
- c. Check oxygen concentration every 2 years to verify the continuing OCSI function.

The manufacturer's instructions for the **preventive maintenance** of the devices are defined in the maintenance manual and any updates to it must be followed.

The work must be carried out by suitably trained technicians.

**Use original spare parts only (see Pg. 7).**

Upon request, the supplier can provide circuit diagrams, spare parts lists, technical details or any other information of use to qualified technical personnel for parts of the device which are designated as being the manufacturer's responsibility or by the manufacturer as repairable.

#### IV. 10. Troubleshooting.

##### Observations

##### Possible Causes

##### Solutions

The <b>I-O</b> (ON/OFF) button is in the " <b>I</b> " (ON) position but the device does not operate. The audible alarm sounds intermittently.	Power cable (9) is not correctly plugged into the wall outlet.  Power failure.	Check the cable connection.  Check the circuit breaker (5) on the front of the unit; Reset if necessary.
Red light remains lighted.	Oxygen concentration is too low.	Contact your equipment supplier.
The alarm test does not work. See IV 4.1.	Capacitor is not charged  Internal electrical fault.	Backup capacitor has discharged Operate unit for approximately 10 minutes and retest Contact your equipment supplier.
The compressor operates and the <b>I-O</b> (ON/OFF) button is in the " <b>I</b> " (ON) position but the green indicator is not lighted.	Faulty indicator.	Contact your equipment supplier.
The <b>I-O</b> (ON/OFF) button is in the " <b>I</b> " (ON) position but there is no flow. The audible alarm sounds continuously.	Pneumatic connection broken or other pressure problem.	Stop the device by pressing the <b>I-O</b> (ON/OFF) button and contact your equipment supplier.
The <b>I-O</b> (ON/OFF) button is in the " <b>I</b> " (ON) position, the compressor is operating and there is a flow but the audible alarm sounds continuously.	Internal electrical fault. Pneumatic circuit fault.	Stop the device and contact your equipment supplier.
The compressor stops in mid-cycle, then starts again after a few minutes.	Compressor thermal safety device has been activated.  Dirty Filters.  Fan is not working.	Stop the device and wait for it to cool down.  Clean cabinet filter. Restart.  Reset circuit breaker. If the device does not start, contact your equipment supplier.
The oxygen enriched air flow is interrupted at the nasal cannula outlet.	Tube disconnected or humidifier cap is not tight.	Check that tubing connections are secure and that the humidifier is sealed.
The flow at the nasal cannula outlet is irregular.	Cannula tubing is kinked or restricted.	Straighten the tubing; contact your equipment supplier if damaged.



##### Maintenance Items

Cabinet Air Filter: Part Ref: 8400-1025; Replace annually, clean every week.

Inlet Air Filter: Part Ref: 8400-1180; Replace annually, more often in dusty environment.

## Appendix: EMC Information

**Important:** Failure to follow these guidelines listed may result in increased emissions and/or decreased immunity of the Nuvo Lite MARK 5 concentrator.

- \* Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- \* Portable and mobile RF communications equipment can affect Medical Electrical Equipment
- \* The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased Emissions or decreased Immunity of the Nuvo Lite MARK 5.
- \* The Nuvo Lite MARK 5 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Nuvo Lite MARK 5 should be observed to verify normal operation in the configuration in which it will be used.
- \* Use only Nidek replacement electrical parts.

<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions:</b> The <b>Nuvo Lite MARK 5</b> is intended for use in the electromagnetic environment specified below. The user of the <b>Nuvo Lite MARK 5</b> should assure that it is used in such an environment.		
<b>Emission tests</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The Nuvo Lite MARK 5 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The <b>Nuvo Lite MARK 5</b> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low - voltage power supply network, that supplies buildings used or domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

**Guidance and manufacturer's declaration – electromagnetic immunity:** The **Nuvo Lite MARK 5** is intended for use in the electromagnetic environment specified below. The user of the **Nuvo Lite MARK 5** should make sure that it is used in such an environment.

<b>Immunity Test</b>	<b>IEC 60601 Test Levels</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment - Guidance</b>
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient/Burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines Not applicable. No I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle  40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5  70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles  <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle  40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5  70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles  <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.  If the user of the Nuvo Lite MARK 5 requires continued operation during power mains interruptions, it is recommended that the Nuvo Lite MARK 5 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U<sub>T</sub> is the a.c. mains voltage prior to application of the test level

**Guidance and manufacturer's declaration – electromagnetic immunity:** This Nuvo Lite MARK 5 is intended for use in the electromagnetic environment specified below. The user of this **Nuvo Lite MARK 5** should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Levels	Compliance Level	Electromagnetic Environment-Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Mark 5 Nuvo Lite, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			<b>Recommended separation distance</b>
Conducted RF	3 Vrms	3 Vrms	$d = 1.2 \sqrt{P}$
IEC 61000-4-6	150 kHz to 80 MHz		
Radiated RF	3 V/m	3 V/m	$d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$
IEC 61000-4-3	80 MHz to 2.5 GHz		$d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b.
			Interference may occur in the vicinity of equipment marked with the following symbol:

**NOTE 1:** At 80 MHz and 800 MHz, the higher frequency range applies.:.

**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electro-magnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MARK 5 **Nuvo LITE** is used exceeds the applicable RF compliance level above, the **Nuvo Lite MARK 5** should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Nuvo Lite MARK 5**.}

b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

#### Recommended separation distances between portable and mobile RF communications equipment and the

**Nuvo Lite MARK 5** device: The Nuvo Lite MARK 5 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Nuvo Lite MARK 5 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Nuvo Lite MARK 5** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (M)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**Note 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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